

restricted groups are, in fact, distinct. Applicant further traverses the restriction requirement because there is clearly no additional burden on the Office if the restriction requirement is not made.

Specifically, Applicants object to the Office's characterization of the special technical features inherent in the subject claims:

With regard to the claims of Groups I and II, all of these claims are drawn to compositions of matter. Moreover, it is beyond all argument that "human sperm," as recited in Claim 58, falls within the generic term "mammalian sperm" as recited in Claim 1. Thus, all of Claims 1 and 34-71 are drawn to compositions of matter comprising mammalian sperm, at least two agents selected from the group consisting of calcitonin, angiotensin II, and/or a modulator of adenosine receptor activity. The Office itself has said as much in its own characterization of these claims. How, therefore, can it be asserted that these two groups of claims lack a corresponding special technical feature?

In support of the restriction between the claims of Groups I and II, the Office states that these groups of claims "are drawn to two distinct products, such as a composition with chemical agents and a composition with human sperm." Applicants submit that the reason offered by the Examiner is insufficient to show that the claims of Groups I and II lack a unifying inventive concept. As a matter of fact, all of the claims of Groups I and II are drawn to compositions of matter that include, as a common element, two agents selected from the group consisting of calcitonin, angiotensin II, and a modulator of adenosine receptor activity. Thus, Applicant submits that it is entirely improper to conclude that the claims of Groups I and II as set forth by the Office are drawn to distinct inventive concepts because these claims share a core composition.

Applicants therefore request that in addition to the elected Group I, that the claims of Group II be examined at the same time.

With respect to the claims of Groups III and IV, the Office states that the method of Claims 72-78 (Group III) and the method of Claims 79-85 (Group IV) are distinct because "they require distinct systems of application, such as *in vivo* and *in vitro* environments." Applicant submits that the reason offered by the Examiner is insufficient to support a

conclusion of patentable distinctness between these two groups of claims. Why does the route of administration render these claims patentably distinct? Does a pharmaceutically active compound become distinct if it is administered intravenously vs. intramuscularly? In short, the Office has not provided any rationale as to why an *in vivo* treatment is patentably distinct from an *in vitro* treatment. It is insufficient merely to identify mutually exclusive groups of claims and restrict them on that basis alone. The Office must supply some reason and/or examples to support the conclusion of patentable distinctness. Therefore, Applicant submits that the restriction between Groups III and IV is improper and should be withdrawn.

Regarding the Claims of Group I-IV and U.S. Patent No 5,698,549, Applicant traverses this portion of the rejection as being unfounded. The composition as recited in Claim 1, for example, is directed to two out of the three recited elements and is directed to a pharmaceutical composition for increasing the capacitation of mammalian sperm. The composition described in the '549 Patent is wholly unrelated to capacitation of mammalian sperm, and is thus non-analogous art to the inventive concept set forth in the claims.

The Office has provided no reasons or examples to support the conclusion of patentable distinctness between Group V and either of Groups I or II. Applicant therefore traverses this portion of the restriction requirement as lacking a proper foundation.

Applicants therefore submit that the restriction requirement is improper and respectfully request that the entire restriction requirement be withdrawn.

Applicants submit that the application is now ready for examination on the merits. Early notification of such action is earnestly solicited.

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